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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,884	07/14/2003	Victor E. Shashoua	N0260.70058US00	5880

7590 09/09/2005

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,884	SHASHOUA ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/14/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 17 December 2004 has been received and entered. Claims 15-17 and 19 have been amended.

Claims 1-19 are presented for examination

Information Disclosure Statement

The information disclosure statement filed 14 July 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Regarding the cited foreign patent documents and non-patent literature, if applicant has submitted these references in a prior application, kindly inform the examiner where these references can be found. They will be considered and a signed copy will be provided to applicant with the next office action.

Claim Objections

Claims 1 and 18 are objected to because of the following informalities: the word *cis*-docosahexanoic acid (sic) is misspelled in each of the claims. The correct spelling is *cis*-docosahexaenoic acid. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not understood what is meant by "fiber system tissue". Does this mean muscle tissue? Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al U.S. Pat. No. 5,925,669 A.

The claims appear to be drawn to a method for targeting a drug to a non-central nervous system tissue to treat a non-central nervous system condition comprising administering a covalent conjugate of *cis*-docosahexaenoic acid (DHA) and a pharmaceutical agent effective for treating a non-central nervous system condition. Katz et al. teach the use of pharmaceutical compositions containing DHA as a carrier for anti-neoplastic drugs (column 6, lines 20-25) for the treatment of lung cancer, breast cancer, colon cancer, prostatic carcinoma, leukemia and brain cancers (column 6, lines 43-52).

It differs in that the particular cis-docosahexaenoic acid type agents are not all recited in the patent. It does however teach that anti-neoplastic agents such as taxol are delivered in a carrier that are natural or synthetic glycerol derivatives containing the docosahexaenoyl group at levels between 25% and 100% by weight based on the total fatty acid content. This appears to be inclusive of the docosahexaenoic acids instantly claimed. It would have been made obvious to one of ordinary skill in art at the time it was made to employ cis-docosahexaenoic acid conjugates as carriers for anti-neoplastic agents motivated by the teaching of Katz et al. who teaches that these docosahexaenoyl type fatty acids are desirable as carriers for anti-neoplastic agents to inhibit the proliferation of malignant cells, control the growth of malignant neoplasms,

prolong remission time and the survival time of a mammal, kill malignant cells and adversely affect malignant cells (column 6, lines 9-19)

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4, 6 18 and 19 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 6, 7 and 8 of prior U.S. Patent No. 6,602,902 B2. This is a double patenting rejection. The inventions are drawn to the identical subject matter, although the wording of instant claim 1 differs very slightly from the wording of conflicting claim 1 in that the word "pharmaceutical agent" is substituted for the word "drug". Since a pharmaceutical agent is also known as a drug, the instant claims conflict with the claims of the patent.

Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,795,909. Although the conflicting claims are not identical, they are not patentably distinct from each other because the treatment of mammalian cell proliferative disorders would include treating the conditions of claims 1-17 of the application such as breast, ovarian and gastrointestinal proliferative disorders. Note also that the claims of the instant application encompass the claimed conjugates. To use cis-docosahexaenoic acid to treat conditions calling for treatment in the breast tissue, gastrointestinal tissue and ovarian tissue would be obvious.

Claims 18 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,080,877. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical preparation comprising a covalent conjugate of cis-docosahexaenoic acid and a non-central nervous system active agent and a pharmaceutically acceptable carrier is encompassed in the claims of the patent which is drawn to a composition of matter comprising a covalent conjugate of cis-docosahexaenoic acid and taxotere. The pharmaceutical preparations of the instant

application would have been obvious from the pharmaceutical compositions in the patent since taxotere is a non-central nervous system agent.

Claims 18 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,919,815. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical preparation comprising a covalent conjugate of cis-docosahexaenoic acid and a non-central nervous system active agent and a pharmaceutically acceptable carrier is encompassed in the claims of the patent which is drawn to a composition of matter comprising a covalent conjugate of cis-docosahexaenoic acid and paclitaxel. The pharmaceutical preparations of the instant application would have been obvious from the pharmaceutical compositions in the patent since paclitaxel is a non-central nervous system agent.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
Patent Examiner
Art Unit 1614

08/24/2005

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